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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/042,930 | 10/18/2001 | Markus Seyfried | 9342-029-999 | 5320 |

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/042,930 | Applicant(s) SEYFRIED ET AL. | |
| | Examiner David J. Steadman | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,46-53 and 57-62 is/are pending in the application.
- 4a) Of the above claim(s) 60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,46-53,57-59 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 1-4, 46-53, and 57-62 are pending in the application.
- [2]** Applicant's cancellation of claims 54-56, amendment to the specification and claims 1, 3, 4, and 49, and addition of claims 60-62 in Paper No. 5, filed March 18, 2003, is acknowledged.
- [3]** Applicant's arguments filed in Paper No. 5 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.
- [5]** Newly submitted claims 60 and 61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The culture or cells of claim 60 and the progeny thereof of claim 61 are distinct from the methods of claims 1-4, 46-53, 57-59, and 62 as the culture or cells of claims 60 and 61 can be used for processes other than methods of converting glycerol to 1,3-propanediol such as a host cell for heterologous protein expression.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60 and 61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112, First Paragraph

- [6]** Claims 1-4, 46-53, 57-59, and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 1 (claims 2-4, 46-53, 57-59, and 62 dependent therefrom) recite the phrase "species of *Thermofrarium*". There is no clear support in the specification,

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claims, or drawings as originally filed for a "species of *Thermofranchium*". It appears that the recitation of "*Thermofranchium*" may be a spelling error as the specification provides support for the term "*Thermobranchium*" at page 21, line 13 of the instant specification. It is suggested that applicant remove the new matter from the claim.

[7] The written description rejection of claims 1-4, 46-53, 57-59, and 62 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 6 of Paper No. 4). Applicant argues (beginning at page 7 of Paper No. 5) the claims have been amended to recite a particular species of thermophilic organism. Applicant argues the 16S rRNA of strain PTA-584 shares 91.7% to 94.1% similarity to previously described species of genera *Caloramator* and *Thermofranchium*. Applicant argues the 16S rRNA sequence of PTA-584 is accessible as Accession Number AF181848 and further argues that the specification teaches how to make the recited species of thermophilic organisms. Applicant's argument is not found persuasive. It is noted that applicant's argument is partially directed to the scope of enablement rejection and not the instant written description rejection. The examiner has responded to applicant's argument to the extent it applies to the instant written description rejection. It is the examiner's position that the specification fails to describe a representative number of species of thermophilic organisms of species *Caloramator*, *Caloramator viterbiensis*, or *Thermofranchium* that convert glycerol to 1,3-propanediol or polyesters produced from 1,3-propanediol to adequately describe the recited genera. Regarding the genus of thermophilic organisms of species *Caloramator* or *Thermofranchium* or the genus of thermophilic strains of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 with the ability to convert glycerol to 1,3-propanediol, the specification discloses only a single representative species of a genus of thermophilic organisms of species *Caloramator*, *Caloramator viterbiensis*, or *Thermofranchium* that convert glycerol to 1,3-propanediol, i.e., PTA-584. No other representative species of thermophilic organisms of species *Caloramator*, *Caloramator viterbiensis*, or *Thermofranchium* with the ability to convert glycerol to 1,3-propanediol have been disclosed. The written description requirement for a claimed genus may be satisfied through sufficient description of a

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representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. The specification fails to provide such a representative number of species of thermophilic organisms of species *Caloramator*, *Caloramator viterbiensis*, or *Thermofrarium*. As stated in a previous Office action, Stackebrandt (*Phylogeny Based on 16S rRNA/DNA*, Encyclopedia of Life Sciences, pages 1-7, Nature Publishing Group, New York, 2001) teaches that only a minor change in the 16S rDNA sequence of a prokaryotic organism (1 % or approximately 15 nucleotides) may significantly alter the physiological and biochemical properties of the organism (page 7). Based on the teachings of Stackebrandt, a skilled artisan would recognize the genera of thermophilic organisms of species *Caloramator* or *Thermofrarium* that convert glycerol to 1,3-propanediol having 16S rDNA that is 95% or 99% identical to that of PTA-584 encompass species that are widely variant and, as evidenced by Stackebrandt, it is highly unpredictable as to the biochemical characteristics – if any – that would be shared by the genera of organisms. Furthermore, the relevant identifying characteristics of a strain of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 with the ability to convert glycerol to 1,3-propanediol are insufficient to describe the entire genus of recited thermophilic *Caloramator viterbiensis* organisms as a skilled artisan would recognize that such characteristics encompass widely variant species. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In this case, more evidence is required to show possession of the claimed genus. Regarding the genus of polyesters produced by conversion of 1,3-propanediol, the specification discloses only a single species of polyester produced from 1,3-propanediol, i.e., PPT. The specification fails to describe any other representative species of polyesters that may be produced from 1,3-propanediol. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and

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exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

[8] The scope of enablement rejection of claims 1-4, 46-53, 57-59, and 62 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 7 of Paper No. 4). Applicant argues (beginning at page 7 of Paper No. 5) the claims have been amended to recite a particular species of thermophilic organism.

Applicant argues the 16S rRNA of strain PTA-584 shares 91.7% to 94.1% similarity to previously described species of genera *Caloramator* and *Thermofranchium*. Applicant argues the 16S rRNA sequence of PTA-584 is accessible as Accession Number AF181848 and further argues that the specification teaches how to make the recited species of thermophilic organisms. Applicant's argument is not found persuasive. It is noted that applicant's argument is partially directed to the written description rejection and not the instant scope of enablement rejection. The examiner has responded to applicant's argument to the extent it applies to the instant scope of enablement rejection. It is the examiner's position that undue experimentation would be required for a skilled artisan to make the entire scope of the invention, particularly the broad scope of: 1) thermophilic organisms of species *Caloramator* or *Thermofranchium* having 16S rDNA that is 95% or 99% identical to that of PTA-584 or the thermophilic strains of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 with the ability to convert glycerol to 1,3-propanediol and 2) polyesters that can be produced from 1,3-propanediol. The specification provides guidance in the form of a single working example of the broad scope of recited thermophilic organisms of species *Caloramator* or *Thermofranchium* having 16S rDNA that is 95% or 99% identical to that of PTA-584 or thermophilic strains of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 with the ability to convert glycerol to 1,3-propanediol, i.e., PTA-584. As stated in a previous Office action, Stackebrandt (*Phylogeny Based on 16S rRNA/DNA*, Encyclopedia of Life Sciences, pages 1-7, Nature Publishing Group, New York, 2001) teaches that only a minor change in the 16S rDNA sequence of a prokaryotic organism (1 % or approximately 15 nucleotides) may significantly alter the physiological and biochemical properties

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of the organism (page 7). As such, a skilled artisan would recognize the high degree of unpredictability that an organism having 16S rDNA that is 95% or 99% identical to that of PTA-584 would maintain the ability to grow under thermophilic conditions and/or convert 1,3-propanediol to glycerol. The specification fails to provide additional guidance regarding the conditions for converting glycerol to 1,3-propanediol using a *Caloramator* or *Thermofranchium* having 16S rDNA that is 95% or 99% identical to that of PTA-584, with significantly altered physiological and biochemical properties. Furthermore, there is no indication in the specification or the prior art that any strain of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 would have the ability to convert glycerol to 1,3-propanediol – particularly those *Caloramator viterbiensis* with altered 16S rDNAs as evidenced by Stackebrandt. Based on the lack of working examples of thermophilic organisms reported to have the ability to convert glycerol to 1,3-propanediol and the teachings of Stackebrandt, one of skill in the art would recognize the high degree of unpredictability that *any* thermophilic organism of the species *Caloramator* or *Thermofranchium* having 16S rDNA that is 95% or 99% identical to that of PTA-584 or the thermophilic strains of *Caloramator viterbiensis* having a growth temperature range for growth of 33-64 degrees Celsius at pH 6.0 would have the ability to convert glycerol to 1,3-propanediol and undue experimentation would be required to make the entire scope of recited thermophilic organisms.

Regarding the scope of polyesters that can be produced from 1,3-propanediol, the specification provides only a single working example of polyesters that can be produced from 1,3-propanediol, i.e., PPT. In view of the lack of guidance for other making other polyesters from 1,3-propanediol, the specification fails to provide the guidance necessary to enable the entire scope of the claimed invention. In view of the lack of guidance provided by the specification, the skilled artisan would be left to determine those additional polyesters – if any – and the conditions for production thereof for generation of polyesters from 1,3-propanediol. Without the necessary guidance for generating polyesters other than PPT from 1,3-propanediol, such experimentation would clearly constitute undue experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of

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the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Double Patenting

[9] At the time of drafting the instant Office action, Application No. 09/405,692 has been abandoned. Therefore, the provisional rejections of claims 1, 2, and 46-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 71-79 of co-pending Application No. 09/405,692 is withdrawn. It is noted that, if Application No. 09/405,692 is revived, the instant provisional rejection may be reinstated.

[10] As stated above, at the time of drafting the instant Office action, Application No. 09/405,692 has been abandoned. Therefore, the provisional rejection of claims 3 and 4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of co-pending Application No. 09/405,692 in view of Doerr et al. (US Patent 5,340,909) is withdrawn. It is noted that, if Application No. 09/405,692 is revived, the instant provisional rejection may be reinstated.

Conclusion

[11] Claims 1-4, 46-53, and 57-62 are pending.

[12] Claims 60 and 61 are withdrawn from consideration.

[13] Claims 1-4, 46-53, 57-59, and 62 are rejected.

[14] No claim is in condition for allowance.

[15] The examiner requests that applicants provide a copy of all pending claims in the response to this Office action.

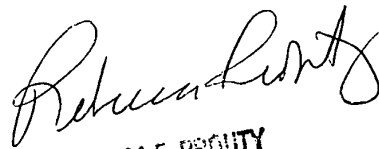
Applicant's amendment to claim 1 necessitated the new matter rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652



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